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नेत्र शल्य क्रिया उपकरण – तनावमापी – विशिष्टि

Indian Standard

EYE SURGERY INSTRUMENTS — TONOMETERS-SPECIFICATION

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

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Price Group 10

Eye Surgery Instruments Sectional Committee, MHD 5

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Stardards on 20 March 1990, after the draft finalized by the Eye Surgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

The tonometer is one of the most important measuring instruments for the detection and diagnosis of 'glaucoma'. The term 'glaucoma' indicates disease of the eye which may show rise in intraocular pressure (IOP) as one of the common symptoms and if allowed to develop, may lead to lesions of the optic nerves and thus to scotomata and even blindness. The development of glaucoma can follow a rise in IOP before pathological changes occur in the fundus of the eye. The indirect measurement results obtained with tonometers represent a close approach to the actual IOP.

The assessment of the IOP becomes more complicated because each of the indirect methods, owing to the contact with the eye as a physical system, effects a change of volume and thus a pressure change as a result of the force exerted on the eye during the measurement procedure. Hence, the user does not measure the IOP in an unstressed eye but rather an increased pressure, raised more or less by the measuring procedure.

This Indian Standard deals with all types of instruments, designed to measure IOP. It lays down both test methods and physical criteria. A tonometer may employ different parameters in order to assess IOP indirectly. Moreover, within a given type, variation in specific design are anticipated. Therefore, each type/design may require a test method unique to the design of the instrument and its physical criteria. This standard, however, does not preclude other types or designs, which are not covered in it. Rather this standard would be amended/revised, if it is felt that new suitable type/design of tonometer has been developed.

In the preparation of this standard, sufficient assistance has been derived from ISO/DIS 8612 'Tonometers', issued by the International Organization for Standardization.

Indian Standard

EYE SURGERY INSTRUMENTS — TONOMETERS - SPECIFICATION

1 SCOPE

1.1 This standard covers the requirements for impression tonometers of the mechanical and mechanical-electrical type as well as applanation tonometers of the mechanical-optical, mechanical-electrical and pneumatic types.

1.2 The different principles of tonometery are described in Annex A.

1.3 Procedures for verifying requirements laid down for tonometers along with recommended proforma for test certificate are specified in Annexes B to D.

2 TYPES

2.0 Tonometers shall be of five types.

2.1 **Type A — Mechanical impression Tonometers**

Instruments which measure the deformation of the cornea, resulting from the application of the tonometer or the tonometer measuring head, that is, the sinking in of the plunger, reading in scale divisions or units or in a recording.

2.2 **Type B — Mechanical-Electrical Impression Tonometers**

Instruments which measure the deformation of the cornea, resulting from the application of the tonometer or the tonometer measuring head, that is, the sinking in of the plunger, reading in scale divisions or units or in a recording.

2.3 **Type C — Mechanical-Optical Applanation Tonometere**

Instruments which measure either the force necessary to flatten the cornea with a pressure body to a diameter between 2’5 and 4’0 mm, depending on the type of instrument, or the diameter -of the applanation circle at known measuring force, indicated in scale divisions or units or in a recording.

2.4 **Type D — Mechanical-Electrical Applanation Tonometers**

Instruments which measure the force necessary to flatten the cornea with a measuring head to a fixed diameter of the circle given by the tonometer type. The force or the pressure is indicated in scale divisions or units or in a recording.

2.5 **Type E — Air Impulse (-Pneumatic) Applanation Tonometers**

Instruments which measure either the time to flatten the cornea by a defined air impulse or the force of an air impulse impinging on the cornea. The measured values are indicated in digits or units or in a recording. This standard only covers air impulse applanation tonometers.

3 GENERAL REQUIREMENTS

3.1 The mechanical parts of the tonometers shall be composed of material with sufficient mechanical resistance and invariability.

3.2 The electrical parts of the tonometers shall be composed of material with sufficient mechanical resistance and electrical invariability.

3.3 The parts of the tonometer which come into contact with the cornea shall be composed of rust-free and acid-resistant steel or of material which is inert to tissues.

4 REQUIREMENTS ON VALUES, DIMENSIONS, TOLERANCES, LIMITS OF ERROR AND PHYSICAL CHARACTERISTICS

4.1 Mechanical Impression Tonometers

4.1.1 *Effective Weight on Plunger*

The effective weight of the lever-pointer system on the plunger when the tonometer is in a vertical position shall be as follows:

$5{\cdot}5 \pm 0{\cdot}15$ g, when indicating scale division ‘5’

$5{\cdot}5 \pm 0{\cdot}20$ g, when indicating scale division ‘10’

4.1.2 *Total Mass and Additional Weights*

The total mass of the tonometer, without handle, shall be $16{\cdot}5 \pm 0{\cdot}5$ g.

The additional weights shall be as follows:

Additional weight with inscription 7’5 : 2’0 $\pm 0{\cdot}02$ g

Additional weight with inscription 10’0 : 4’5 $\pm 0{\cdot}02$ g

Additional weight with inscription 15’0 : 9’5 $\pm 0{\cdot}02$ g

4.1.3 *Friction Between Plunger and Plunger Sleeve*

If the tonometer is moved slowly and uniformly from the horizontal position into the vertical position, while the plunger is on the upper stop, the plunger shall begin to slide into the footplate hole at an angle of the tonometer axis to the horizontal not exceeding 25”. During this manoeuvre the lever shall not touch the plunger.

The tonometer shall be able to slide easily in its handle.

4.1.4 *Dimensions of Footplate and Plunger*

The dimensions of the footplate and plunger shall be given in Tables 1 and 2 respectively.

Table 1 Dimensions of Footplate

(*Clauses* 4.1.4 *and* 4.2.4)

	Feature of Footplate	Dimension mm
	Diameter	10’1 ± 0’2
	Radius of curvature of the spherical front surface	15·0 ± 0’25
	Outside diameter of the spherical front surface (d_{Min})	9·0 *Min*
Either	Diameter of the recess or counterbore on the front surface up to a height of 1·5 mm *Min*	3’0 *Max*
	Or	
	Radius of the inside edge curvature	0·2 *Mux*
	Or	
	Diameter of the circle at the transition between footplate curvature and edge curvature of the recess or counterbore (central area) (d_1^c)	3·7 *Max*

Table 2 Dimensions of Plunger

(*Clauses* 4.1.4 *and* 4.2.4)

Feature of Plunger	Dimension mm
Diameter at the front surface up to a height of 1·5 mm, *Min*	3’0 ± 0 03
Radius of curvature of the spherical front surface	15’0 ± 0’75
Radius of the edge curvature	0’25 ± 0·015
Extension of the plunger below the footplate (h_{Max})	3’0 *Max*

4.1.5 *Surface Condition*

The front surfaces of the footplate and of the plunger shall be smooth and shall not have any irregularities. The outside edge of the front surface of the footplate and the inside edge at the recess or counterbore shall be rounded.

4.1.6 *Zero Point*

The zero point of the impression tonometer with concave plunger base shall be defined in terms of the tangent plane of the plunger. The tangent plane of the plunger is the plane perpendicular to the axis of the plunger and tangent to the edge radius of the plunger. The plunger is in the position corresponding to zero on the tonometer scale, when the perpendicular distance from the tangent plane of the plunger to the centre of curvature of the footplate is equal to that radius of this concavity -0’102 mm.

4.1.7 *Scale*

The scale shall be divided into at least 15 equal scale divisions (— I to 15 or 0 to 15 respectively), the distance between two lines shall be equal to a plunger displacement of 0’05 mm, so that the displacement of the plunger is equal to the values given in either Table 3A or 3B depending on the scale divisions. The scale shall show whole numbers only.

Table 3A Plunger Displacement for Scale from -1

(*Clauses* 4.1.7 *and* 4.2.7)

All dimensions in millimetres.

Scale Division		Plunger Displacement Values
From	To	
- 1	5	0’30 ± 0’01
- 1	10	0·55 ± 0’02
— 1	15	0’80 ± 0’03
— 1	18	0’95 ± 0’05

Table 3B Plunger Displacement for Scale from 0

(*Clauses* 4.1.7 *and* 4.2.7)

All dimensions in millimetres.

Scale Division		Plunger Displacement Values
From	To	
0	5	0’25 ± 0·01
0	10	0’50 ± 0·02
0	15	0’75 ± 0’03
0	18	0·90 ± 0’05

The division of the scale shall consist of lines. The lines shall be straight, of equal width and directed in the axis of the pointer. No line shall be wider than 1/4 of the distance between two lines nor more than 0’25 mm.

4.1.8 *Pointer*

The pointer shall not be wider than the smallest width of a line in the area of the scale. If the pointer moves over the scale, it shall overlap the shortest lines by at least one-third; the end shall not extend over the scale lines. The distance between pointer and scale shall not be greater than 1’0 mm in the area of the scale.

4.1.9 *Plunger*

The scale may be arranged parallel or inclined to the axis of the plunger.

At some point between scale divisions 5 and 10, the plunger axis and the lower surface of the lever shall form a right angle at the point of contact.

4.1.10 *Testing on Test Block*

If the instrument is tested on a test block with a radius of curvature of 14’75 mm, the pointer shall indicate -1 ± 0’2 on the scale ; when tested on a test block with a radius of curvature of 16 mm, it shall indicate 0 ± 0’2 on the scale.

With the tonometer in position on the test block, the scale reading shall not vary by more than 0’4 scale divisions when the plunger is turned or moved sideways or when the lever on the test block is moved sideways.

4.1.11 *Verticality of Tonometer*

When the tonometer is picked up without being held firm at the holding point of the handle, the axis shall naturally assume a vertical position.

4.1.12 *Recording*

If there is a recording device, the limits of error for the record shall be the same as for the scale readings.

4.2 Mechanical-Electrical Impression Tonometers

4.2.1 *Effective Weight of the Plunger*

The effective weight of the plunger measured with the instrument ready for use shall amount to 5’5 ± 0’1 g within the measuring range and with the measuring head vertical.

4.2.2 *Total Mass and Additional Weights*

The total mass of the tonometer measuring head, without handle, shall be 16’5 ± 0’5 g.

The additional weights shall be as follows:

Additional weights with inscription 7’5 : 2’0 ± 0’02 g

Additional weights with inscription 10’0 : 4’5 ± 0’02 g

Additional weights with inscription 15’0 : 9’5 ± 0’02 g

4.2.3 *Friction Between Plunger and Plunger Sleeve*

If the tonometer measuring head is moved slowly and uniformly from the horizontal position into the vertical position, while the plunger is removed 4 mm, the plunger shall begin to slide into the footplate hole at angle of the tonometer axis to the horizontal not exceeding 25”.

The tonometer shall be able to slide easily in its handle.

4.2.4 *Dimensions of Footplate and Plunger*

The dimensions of the footplate and plunger shall be as given in Tables 1 and 2 respectively.

4.2.5 *Surface Condition*

The front surfaces of footplate and plunger shall be smooth and shall not have any irregularities. The outside edge of the front surface of the footplate and the inside edge at the recess or counterbore shall be rounded.

4.26 Zero *Point*

The zero point of the impression, tonometer with concave plunger base shall be defined in terms of the tangent plane of the plunger. The tangent plane of the plunger is the plane perpendicular to the axis of the plunger and tangent to the edge radius of the plunger. The plunger is in the position corresponding to zero on the tonometer scale when the perpendicular distance from the tangent plane of the plunger to the centre of curvature of the footplate is equal to the radius of this concavity -0’102 mm.

4.2.7 *Scale*

The scale shall be divided into-at least 15 equal scale divisions (— 1 to 15 or 0 to 15 respectively); the distance between two lines shall be equal to a plunger displacement of 0’005 mm, so that the displacement of the plunger is equal to the values given in either Table 3A or 3B depending on the scale divisions. The scale shall show whole numbers only.

If there is a digital read-out in a three-digit display, the last digit shall be changed by one unit due to a displacement of the plunger of not more than 0’005 mm.

The interval between the dividing lines shall be 4 mm or more and may be subdivided. The division of the scale shall consist of lines. The lines shall be straight, of equal width and directed in the axis of the pointer. No line shall be wider than 1/4 of the distance between two lines nor more than 0·25 mm. The scale shall show whole numbers only.

4.2.8 The pointer shall not be wider than the smallest width of a line in the area of the scale. If the pointer moves over the scale, it shall overlap the shortest lines by a least one-third, the end shall not extend over the scale lines.

4.2.9 *Testing on Test Block*

When the tonometer measuring head is placed on a test block having curvature radius of 14’75 mm or 16’00 mm, the scale reading shall be -1’0 or 0’0, respectively, with a tolerance of ± 0’2 of a scale interval or ± 0·2 as indicated by the final digits.

When the tonometer measuring head is placed on the attached test block marked ‘15’, the scale reading shall not exceed 15 with a tolerance of ± 0’2 as indicated by the final digits.

With the tonometer measuring head in position on the test block, the scale reading shall not vary by more than 0’2 scale divisions of ±0·2 as indicated by the final digits (that is, 0’0 1 mm displacement of the plunger), when the plunger is turned or moved sideways.

4.2.10 *Voltage/Temperature Effect on Scale Readings*

4.2.10.1 At temperatures between 15 and 30°C at constant operating voltage, the scale reading within the measuring range shall not vary by more than ±0·2 of a scale interval or ±0·2 as indicated by the final digits (that is, 0’01 mm displacement of the plunger).

4.2.10.2 During a fluctuation in operating voltage of ±10% at 20°C, the scale reading shall not vary by more than ±0·2 of a scale interval or ±0·2 as indicated by the final digits (that is, 0’01 mm displacement of the plunger).

4.2.11 *Recording*

If there is a recording device, the limits of error for the record shall be the same as for the scale readings.

If there is a digital read-out with seven segment indications, means of control shall be provided to test the function of the single segments.

4.3 **Mechanical-Optical Applanation Tonometers**

4.3.1 *Diameter of Applanatian Circle*

Mechanical-optical applanation tonometers which measure the force needed to obtain a given area of applanation shall have a constant value between 2’5 and 4’0 mm for the diameter of the applanation circle.

The tolerance for the diameter of the applanation circle shall be ±0·02 mm.

4.3.2 *Surface of Pressure Body*

The front surface of the pressure body shall be even, polished and free from scratches and shall have a diameter of at least 6·0 mm.

4.3.3 *Measuring Force*

The measuring force shall be continuously adjustable within the range from 0 to 40’0 mN *Min,* without the range being altered and without the use of additional weights. The measured value of the force shall be clearly legible on a linear divided scale.

The change of force required to move the pressure body in the opposite direction (revers span) at the point of transition shall not exceed ±0·29 mN.

4.3.4 *Scale*

Lines shall be used as graduations on the measuring scale. The lines shall be straight, of equal width and durable. No line shall be wider than ¼ of the distance between two lines.

One scale unit shall represent either 0’98 or 1’96 mN. The main scale graduations shall be marked with a value. The width of the reference mark shall not be greater than the smallest width of the graduation lines on the measuring scale.

4.3.5 *Tolerance for Measurement of Force*

When the pressure body is adjusted to the verification position, the tolerance for the measured value of the force within the measuring range shall be ± 1’5 percent of the nominal value, but not less than ±0·49 mN, over a temperature range from 15 to 30°C.

4.3.6 *Recording*

If the measuring force is recorded, the limits of error shall be the same as those specified in 4.3.5.

4.3.7 *Tonometer Used as Limit Gauge*

If the tonometer is to be used as a limit gauge only, the diameter of the applanation circle and the measuring force shall be constant. Tolerances specified in 4.3.1 and 4.3.5 shall apply.

4.4 Mechanical-Electrical Applanation

4.4.1 *Diameter of Applanation Circle*

4.4.1.1 For determination of force required in applanation, the diameter of the applanation circle shall have a constant value not less than 2’5 mm in diameter.

The tolerance for the diameter of the applanation circle shall be ±0·02 mm.

4.4.1.2 For tonometers which measure the diameter of the applanation circle, the force shall be constant. The diameter of the applanation surface shall be measured and the tolerance specified in 4.4.1.1 shall apply.

In determining the pressure (force/surface), the diameter of the applanation surface can be equal to the diameter of the front surface of the measuring head.

4.4.2 *Surface of Pressure Body*

The front surface of the pressure body shall be even, smooth and free of scratches and shall have a diameter of at least 4’5 mm.

4.4.3 *Measuring Force*

The measuring force shall be continuously adjustable within the range from 0 to 49’0 mN *Min*; without the range being altered and without the use of additional weights. The measured value of the force shall be indicated on a linear scale or typed in scale divisions using a recorder, or indicated digitally.

The determination of the force applied to the front surface of the pressure body within the circle of applanation can also be made from a concentric circular plane the diameter of which is equal to or smaller than the radius of the circle of applanation using a mechanical-electrical measuring device.

The change of force required to move the pressure body in the opposite direction (inverse span) at the point of transition shall not exceed ±0'29 mN.

4.4.4 *Scale* (if the force applied to flatten the cornea is recorded on a scale).

Lines shall be used as graduations on the measuring scale. The lines shall be straight, of equal width and durable. No line shall be wider than 1/4 of the distance between two lines nor more than 0'25 mm in width.

One scale unit shall represent either 0'98 or 1'96 mN. The main scale graduations shall be marked with a value. The width of the reference mark shall not be greater than the smallest width of the graduation lines on the measuring scale.

4.4.5 *Pointer* (if the force applied to flatten the cornea is recorded on a scale).

The pointer shall not be wider than the smallest width of a line in the area of the scale. If the pointer moves over the scale, it shall overlap the shortest lines by at least one-third; the end shall not extend over the scale lines.

4.4.6 *Tolerance for Measurement of Force*

When the pressure body is adjusted to the verification position of its range of movement, the tolerance for the measured value of the force within the measuring range shall be ± 1'5 percent of the nominal value, but not less than ±0'49 mN, over a temperature range from 15 to 30°C.

4.4.7 *Recording*

If the measuring force is recorded, the limits of error shall be the same as those specified in 4.4.6.

4.5 Air Impulse Applanation Tonometers

4.5.1 *Indication of Measurements*

The display shall be digital.

> **NOTE-In** use, the value shown on the display should give the numerical value of the force. in millinewtons (mN), which is necessary to flatten the cornea to the given applanation circle of 3'06 mm, similar to the mechanical-optical applanation tonometer described in 4.3 and A-3.

It shall be possible to control the segments of the digital display.

The measuring range shall at least extend from the digit '12' to the digit '50'.

4.5.2 *Dimensions of Nozzle*

The dimensions of the nozzle centred on the optical axis of the objective shall be as given in Table 4.

Table 4 Dimensions of Nozzle

All dimensions in millimetres.

Feature of Nozzle	Dimension
Length	27'305 ± 0'075
Inside diameter	2'413 ± 0'010
Conicity of inside diameter over total length	0'005 Max

4.5.3 *Verification of Display*

For the verification using apparatus such as the one described in Annex D, the corelation between the digital display and the measured value of the force of the air impulses on a face 2'5 mm in diameter at a distance of the test mark in the observer's microscope shall be as given in Table 5. For verification purposes, the eyepiece should be screwed inwards until the focussing graticule is sharply in focus.

Table 5 Correlation Between Digital Display and Measured Values of the Force of Air Impulses

Digital Display Reading	Force of Air Impulses mN	Digital Display Reading	Force of Air Impulses mN	Digital Display Reading	Force of Air Impulses mN	Digital Display Reading	Force of Air Impulses mN
—	—	21	9'0	31	16'0	41	23'0
12	1'5	22	9'7	32	16'7	42	23'7
13	2'3	23	10'4	33	17'4	43	24'4
14	3'7	24	11'1	34	18'1	44	25' 1
15						45	
16	4'6 5'4	26	12'5 11'8	37	19'5 18'8	46	25'8 26'5
17	6'1	27	13'2	38	20'2	47	27'2
18	6'9	28	13'9		20'9		27'9
19						48	
20	7'7 8'3	29 30	14'6 15'3	39 40	21'6 22'3	49 50	28'6 29.3

4.5.4 *Voltage/Temperature Effects on Display*

For the digital display in the temperature range from 15 to 30°C, at constant operating voltage, the maximum permissible errors shall be

-between digit display readings '12' and '30' : ±1 as indicated by the final digits

-between digit display readings '31' and '50' : *12* as indicated by the final digits

During a fluctuation in the operating voltage of ± 10 percent at 20°C, the maximum permissible error shall be ±1 as indicated by the final digits.

NOTE — For reasons of basic measuring principles, digital displays require a different approach to the setting of tolerances. Therefore the digital readings on type A tonometers do not necessarily accord with the corresponding analogue readings on scaled applanation tonometers, but if a type A tonometer meets the test requirements, clinical suitability is ensured.

5 MARKING

5.1 Each tonometer shall be marked with the following information:

a) Type,

b) Indication of the source of manufacture,

c) Country of manufacture, and

d) Serial number.

5.2 On each applanation tonometer with constant diameter of the applanation circle and variable measuring force, the diameter of the applanation circle shall be stated, unless its value is 3’06 mm.

5.3 Each instrument and its requisite accessories, except for the pressure body of the mechanical-optical applanation tonometers and the measuring head of the mechanical-electrical impression tonometers and mechanical-electrical applanation tonometers, shall be marked with an individual serial number. Each tonometer measuring head with its associated plunger shall be identically numbered.

5.4 Calibrating rods or weights, or other graduating equipment shall not be marked.

5.5 Each objective/tube unit shall bear the same number as the air impulse applanation tonometer to which it relates.

5.6 On each air impulse applanation tonometer, the measuring range shall be indicated as given in the following example:

> 'Measuring range in digital notation from 12 to 50'.

6 STORAGE REQUXREMENTS

6.1 Tonometers shall be stored separately in containers together with their respective measuring heads unless the measuring device is connected to the tonometer and is inseparable.

ANNEX A

(*Clause* 1.2)

PRINCIPLES OF TONOMETRY

A-1 GENERAL

A-1.1 The following principles prove clinically useful for the measurement of an accepted correlation of IOP:

a) *Impression Principle*

A plunger deforms the cornea to obtain a state ofquasi-equilibrium between external and internal pressure and where the size of the 'indentation' is measured.

b) *Applanation Principle*

A plane surface is pressed against the cornea so as to determine the force necessary to flatten a defined area (Goldmann principle) or to determine the size of a flattened area subjected to a defined force (Maklakoff principle).

Both principles are based on the Imbert-Fick law, which states that if a plane surface is applied with force F to a thin spherical membrane within which a pressure 'p_t' exists, for an equilibrium condition the fallowing formula is valid:

$$p_t = \frac{F}{A} \qquad \ldots\ldots(1)$$

where

A is the area of the applied surface, and

p_t is the raised pressure due to the measuring procedure (see Fig. 1).

A-2 IMPRESSION TONOMETRY

A-2.1 Friedenwald investigated the relationship between the quotient F/p_t and the extent of indentation (3 and 4). The scale reading R of the tonometer was a measure of this relationship. The result of these measurements is given by:

$$p_t = \frac{F}{a+bR} \qquad \ldots\ldots(2)$$

where a and b are constants. Also see Fig. 2.

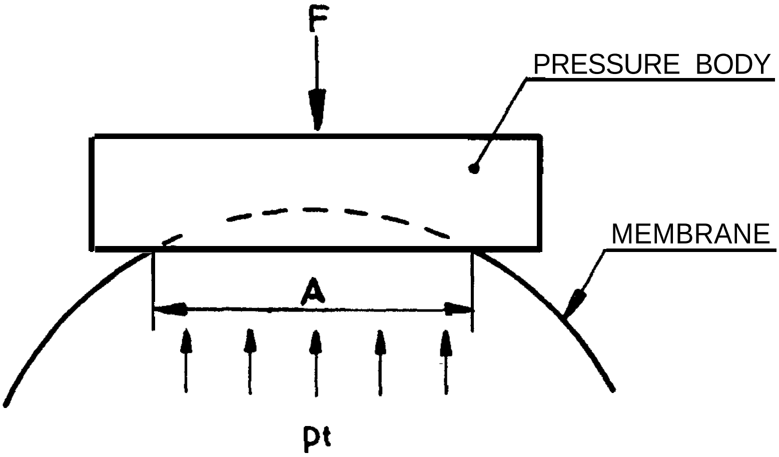


FIG. 1 PRINCIPLE OF TONOMETRY

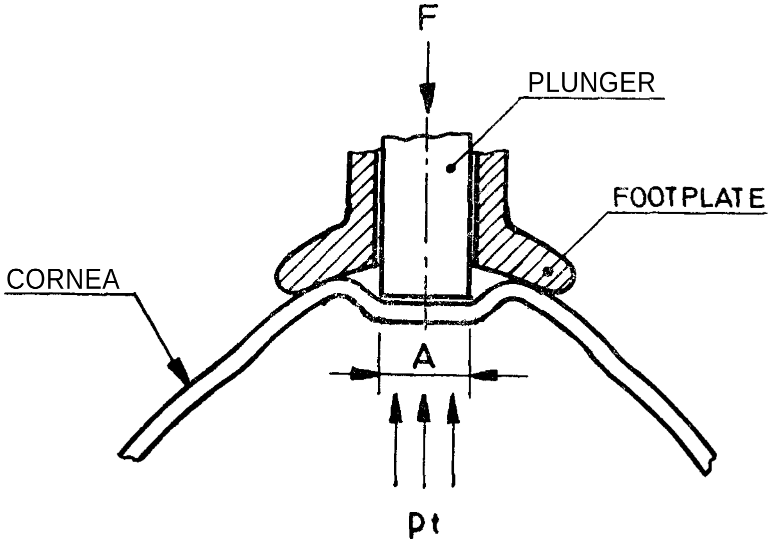


FIG. 2 PRINCIPLE OF IMPRESSION TONOMETRY

However, the pressure p_t determined in this way represents the pressure in the eye under the additional stress produced by the tonometer and the plunger pressure. But knowledge of the pressure p_o in the unstressed eye is more important. Both parameters, pt and p_o could only be interrelated after the concept of 'rigidity' was introduced into the calculations (3). Friedenwald demonstrated empirically that the resistance the eye offers to change in the intraocular pressure can be described by a rigidity coefficient, K, according to the following formula:

$$K = \frac{\log p_t - \log p_o}{\text{- - - - - } E \text{ - -}} \qquad \ldots (3)$$

where V_t is the indentation volume.

If this equation is solved for log p_o andpt is replaced by equation (2), the following basic equation for impression tonometry is thus obtained:

$$\log p_o = \log\text{---}\& \; -KV_t \qquad \ldots (4)$$

So as to avoid a rigidity determination being obligatory for every measurement made, conversion tables were produced (3) and (4) for the pressure/scale-division relationship for practical use of the Schiotz tonometer, using average values for a, b and $K = 0{\cdot}021\,5$ mm^{-3} calculated statistically.

A-3 APPLANATION TONOMETRY

A-3.1 Mechanical-Optical Applanation Tenometry

The theory of applanation tonometry is derived in similar, but theoretically more exact, fashion from the Imbert-Fick law. In this case, owing to the physical properties of the cornea and its wetting liquid, two terms shall be added to formula (1) to give the following equation:

$$p_t = \frac{F}{A} (P_M + P_N) \qquad \ldots (5)$$

where, P_M is a pressure caused by the characteristic rigidity of the eye;

P_N takes into account the pressure which depends on the surface tension of the liquid and the wetting properties of the cornea and flattening surface of the pressure body. Also see Fig. 3.

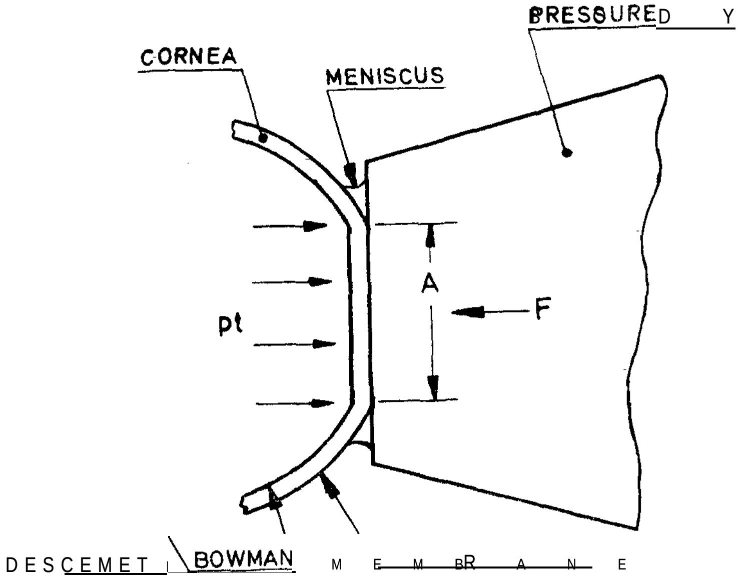


FIG. 3 PRINCIPLE OF APPLANATION TONOMETRY

The rigidity of the eye does not play such an important role in the applanation principle, as it does in the impression principle, since the pressure on the eye is affected by the measuring force alone. For a constant and sufficiently small applanation area, the following simple relationship, derived by **Goldmann** and Schmidt (5), is valid for po **and** pt:

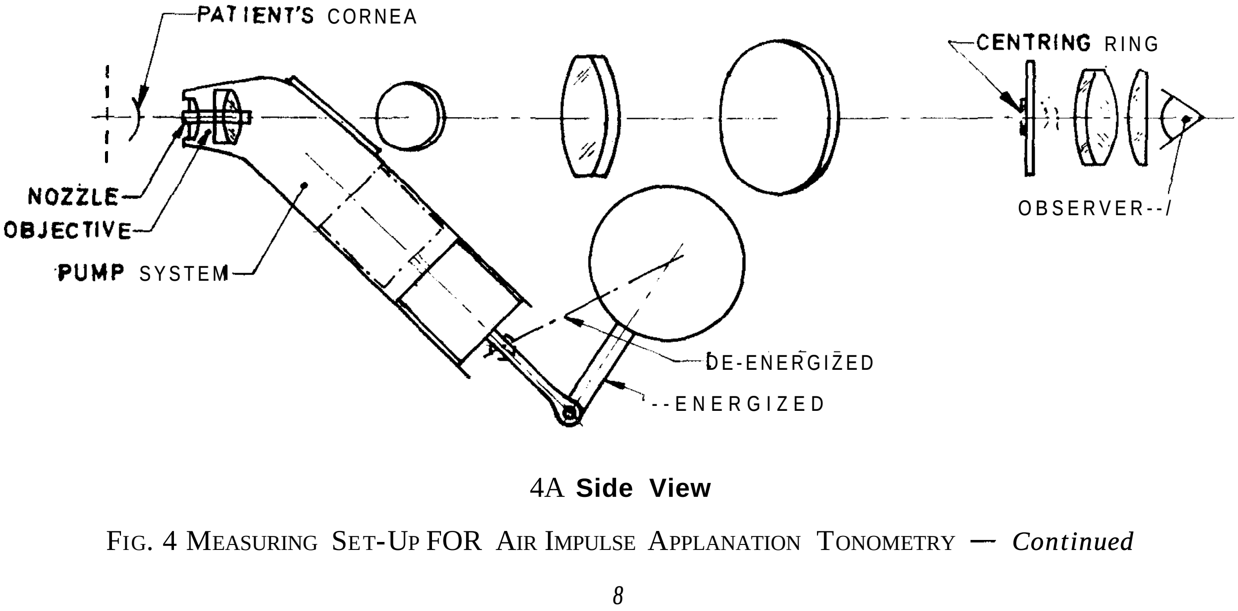
$$pt \; po = 0'98 \; pt$$

It was concluded that, as a good approximation, $po = pt$ is valid for an applanation circle diameter of 3’06 mm.

A-3.2 Air **Impulse Applanation** Tonometry

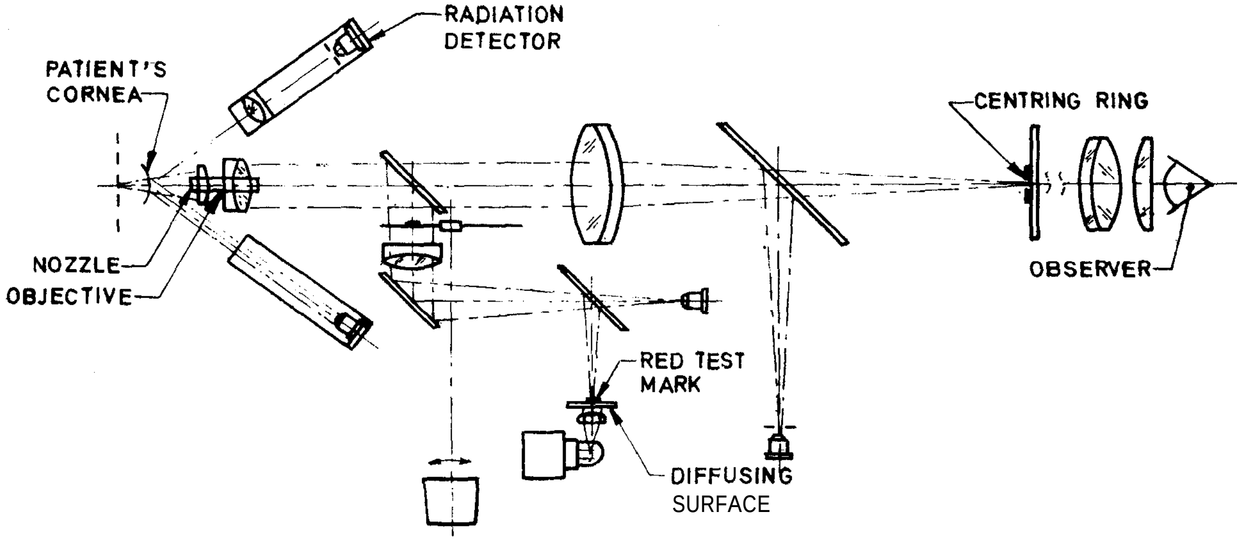
Deviating from the applanation tonometry with constant face and constant measuring force respectively, applanation of the cornea is caused by a defined air impulse. As a correlate of the intraocular pressure, either the time or the force of an air impulse is applied to flatten the cornea.

The tonometer with constant face is classified as type A. The measuring procedure (see Fig. 4) is based on the principle that an air impulse, generated by pump system, passing through a nozzle in the objective, the axis of which coincides with the axis of the objective, falls on to the eye of the patient at about 11 mm distance and deforms the cornea. During the measurements, the deformation of the cornea is increased until the marginal rays (see Fig. 5A and 5B) of a light beam, obliquely incident on the cornea, are **reflected parallel** to the axial ray and the maximum light intensity falls on a radiation detector.



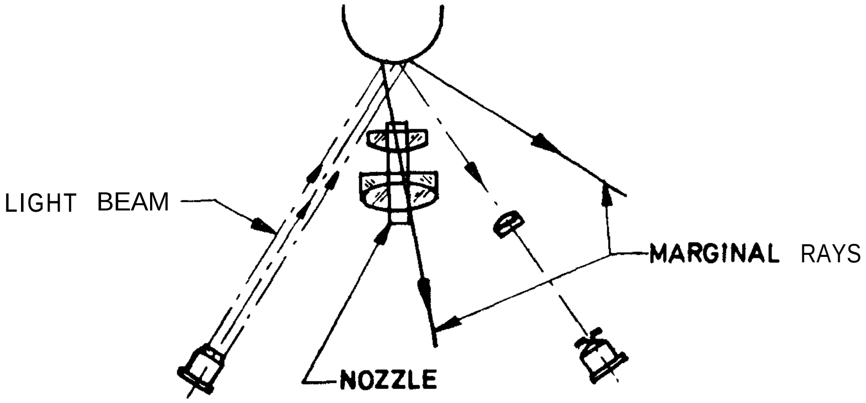
4A **Side View**

FIG. 4 MEASURING SET-UP FOR AIR IMPULSE APPLANATION TONOMETRY — *Continued*

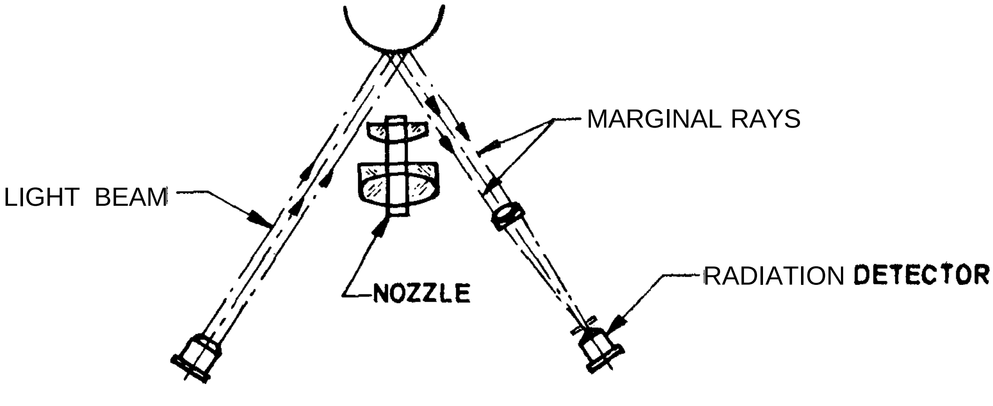


4B Top View

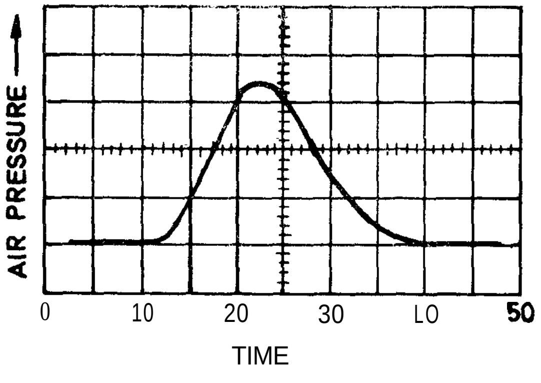
FIG. 4 MEASURING SET-UP FOR AIR IMPULSE APPLANATION TONOMETRY



5A **Reflection** of the Light Beam Before Deformation of Cornea



5B Increase of Deformation Until Marginal Rays are Parallel to Axial Ray



5C Air Impulse Curve

FIG. 5 MEASURING PROCEDURE FOR AIR IMPULSE APPLANATION TONOMETRY

As soon as the cornea is flattened, the electric circuit of the pump system is interrupted. The electronically stopped timing from the beginning of the measuring procedure to the flattening of the cornea is displayed digitally on the observer’s side of the tonometer. The measuring procedure takes place on the linearly rising flank of the air impulse curve in the space of few milliseconds (see Fig. SC).

A test mark (F) (red point on white background) projected on the cornea by means of an optical system serves to align the instrument with the patient’s eye. When the axis of the system is co-incident with the vertex of the cornea, the test mark comes to rest in the alignment position within a centring ring (R), incorporated in the ocular plane of the observer’s microscope. Only if this condition is fulfilled can an impulse release take place. For definition of radial alignment position, see D-2.3.

If, conditioned by the pathological state of the cornea, the test mark can be projected only in a distorted or blurred way, the type A tonometer nevertheless can be released and the digital display flashes. The flashing display indicates that the criteria for measurement were not met.

ANNEX B

(Clause 1.3)

VERIFICATION OF THE REQUIREMENTS LAID DOWN FOR MECHANICAL AND MECHANICAL-ELECTRICAL IMPRESSION TONOMETERS

B-l APPARATUS

B-l.1 Balance

For the determination of the mass of the tonometer without handle, the effective weight of the plunger loaded by the Lever-pointer system and the determination of the plunger displacement (transmission ratio).

B-l.2 Analytical Balance

For the examination of the additional weights reading 7’5, 10’0 and 15’0, having a sensitivity of 0·002 g per scale division.

B-l.3 Measuring Equipment

For testing the friction between plunger and plunger sleeve.

B-l.4 Measuring Equipment

For testing the curvature of the spherical front surfaces of the footplate and plunger.

B-l.5 Measuring Equipment

For testing the transition circle (central area), including an optical limit gauge consisting of two lines whose distance from each other corresponds to the permitted dimensional tolerance limits for transition circle specified in 4.1.4 or 4.2.4.

B-l.6 Projector

With magnification **x 50,** and optical limit gauge consisting of two circle sectors the radii of which correspond to the permitted dimensional tolerance limits for the radius of the plunger edge curvature specified in 4.1.4 or 4.2.4.

B-l.7 Micrometer

With support (measuring range at least from 0 to 15 mm, readings of 0’01 mm) for testing the diameter of the footplate and the diameter of the plunger at the front surface.

B-l.8 Limit Gauges

B-1.8.1 Limit gauge, disc-shaped, for testing the outside diameter of the spherical front surface of the footplate.

B-1.8.2 Limit gauge, consisting of a thin circular disc with a radius of 14’75 mm and a radial slot approximately 3·00 mm wide and having a depth corresponding to the permitted dimensional tolerance limit for the extension of the plunger below the footplate specified in **4.1.4 or 4.2.4**.

B-1.8.3 Limit gauge, consisting of a glass plate marked with a standard line the width of which is equal to the permitted maximum width of dividing lines on the scale specified in 4.1.7 and 4.2.7.

B-1.8.4 Slip gauge, manufactured to the permitted maximum limit for the pointer distance from the scale specified in 4.1.8.

B-l.9 Test Spheres

Having a radius of curvature of 14’75 or 16’00 ± 0’003 mm.

B-l .10 Cylindrical Measuring Gauge

Having a diameter of 3·0 mm $\pm 2\ \mu m$, for testing the diameter of the bore or counter bore.

B-l **.11** Cylindrical Measuring Gauge

The diameter of which is slightly smaller than the bore diameter of the tonometer with the plunger removed.

B-2 VERIFICATION PROCEDURES

B-2.1 Effective Weight of the Plunger Loaded by the Lever-Pointer System (see Fig. 6)

Place the desired test weight of 5’5 g on the balance pan 2, and place the tonometer to be tested in the receiving device 4 rigidily fastened to a slide 3. The tonometer centres itself, that is, the measuring point, which on the right side is located vertically on the beam of the balance (see **B-l.1**) 1, shall align with the axis of the plunger. Then adjust the pointer to scale division line ‘5’ or ‘10’, respectively, by lowering or lifting the slide in the guideway 6 with the aid of measuring screw 5 which in this case serves for moving the slide only.

The tonometer shall be deemed to comply with the requirement as regards effective weight, specified in 4.1.1 or 4.2.2, as appropriate, if the reference point 8 found on the eyepiece scale of the measuring microscope 7 within the corresponding tolerance zone.

B-2.2 Displacement of the Plunger (Transmission Ratio) (see Fig. 6)

Keep the tonometer in the same position as specified in B-2.1. Adjust scale division line ‘—1’ on the measuring screw 5 to the reference mark, and load the balance pan 2 with a 16’5 g test weight, whereby the beam of the balance is tensionally connected to the fine-adjusting knurled-head screw 9. Adjust the reading of the tonometer to scale division line ‘—1’ with the aid of the knurled-head screw. The adjustment of the tonometer pointer to the division lines to be tested is obtained by turning the measuring screw, and each time the location of the reference point of the measuring screw with regard to the corresponding tolerance zones on the drum shall be observed.

The observed values shall comply with the requirements specified in 4.2.7.

B-2.3 Mass of the Tonometer (Without Handle) (see Fig. 6)

Lift the slide 3 of the balance (B-l.1). Place a hook 10 on the measuring point of the beam of the balance, the mass of which is compensated by an additional test mass underneath the balance pan 2. Suspend the tonometer on the hook, whereby its handle is lifted as far as the middle of its free motion by the fork 11. Place the 16’5 g test mass is placed on the balance pan 2.

The tonometer shall be deemed to comply with the requirement as regards total mass, specified in 4.1.2 or 4.2.2, as appropriate, if the reference point 8 lies within the corresponding tolerance zone on the eyepiece scale of the measuring microscope 7.

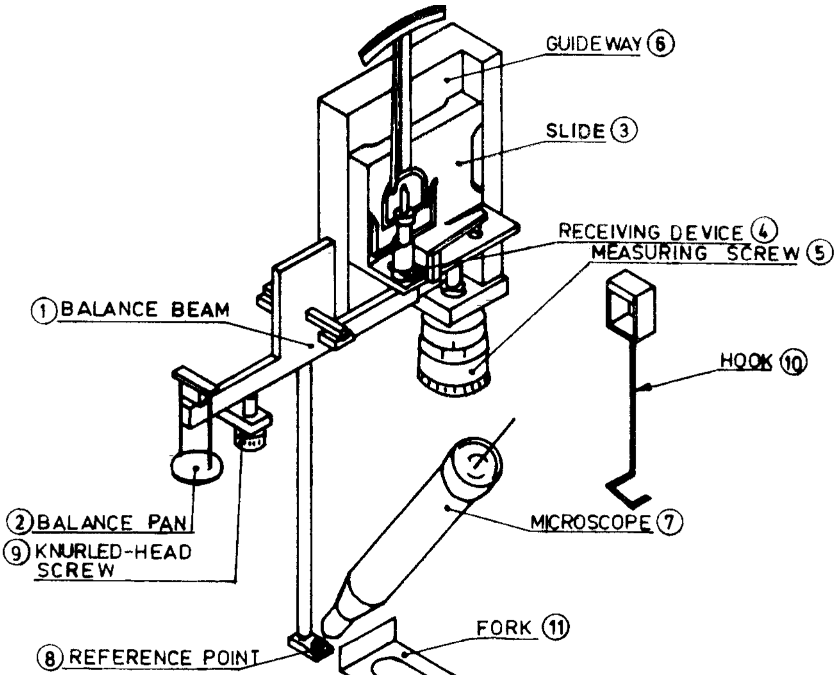


FIG. 6 TEST SET-UP FOR VERIFYING EFFECTIVE WEIGHT OF THE PLUNGER LOADED BY LEVER-POINTER SYSTEM, DISPLACEMENT OF THE PLUNGER AND TOTAL MASS OF TONOMETER (WITHOUT HANDLE)

B-2.4 Additional Weights

They shall be checked by comparison with standard weights on an analytical balance (B-l.2) or an electronic balance.

The values shall comply with the requirements specified in 4.1.2 or 4.2.2 as appropriate.

B-2.5 Friction Between Plunger and Plunger Sleeve

Insert the tonometer into the measuring apparatus (B-1.3; see Fig. 7) by its guide tube, and restrain its lever so that it does not touch the plunger during the movement. After removing the plunger as far as the upper limit stop, or 4 mm in case of the mechanical-electrical impression tonometer, bring the tonometer from the horizontal position into the vertical position.

The same test shall be repeated beginning from the opposite direction..

The tonometer shall be deemed to comply with the requirement specified in 4.1.3 or 4.2.3 as appropriate, if the plunger starts sliding before the angle specified in 4.1.3 or 4.2.3 is reached.

B-2.6 Radii of Curvature of the Front Surfaces of Footplate and Plunger (see Fig. 8)

Suspend the tonometer 9 on the receiver 5. Adjust the measuring disc support 2 so that the desired limit gauge 3 is down, and lift the slide 4 by turning the eccentric 6. The gauge now presses on the footplate with its own mass. The shape of the light slit 8 between gauge and footplate (see Fig. 9A) is a responsive indicator for the determination of whether or not the radius of curvature of the footplate is inside or outside the dimensional requirements specified in Table 1.

NOTE — A stop incorporated in the apparatus allows the slide to move only if a measuring disc is down; thus possible damage to the measuring discs by improper handling of the appliance is avoided.

If the curvature radius of the plunger front surface is to be tested, hold the plunger in position of maximum extension under the footplate and repeat the procedure given above (see Fig. 9B).

The tonometer shall be deemed to comply with the dimensional requirements specified in 4.1.4 or 4.2.4, as appropriate, if the observed values indicated by the shape of the light slit are in accordance with the tolerance limits.

B-2.7 **Diameter of the Transition Circle (Central Area) (d_{tc})**

For verification of the value d_{tc} (see Fig. 10), four test procedures, described in B-2.7.1 to B-2.7.4 are available.

B-2.7.1 Remove the plunger from the tonometer and coat the surface of the footplate with a thin film of Prussian blue. Place the footplate on the 14’75 mm radius test sphere (B-l.9) and rub this sphere against the footplate. When the footplate is removed, a bright circle can be seen. The internal part which is not tinted blue corresponds to the ‘central area’. Determine the diameter with the aid of an optical limit gauge (B-1.5).

B-2.7.2 By looking vertically down onto the footplate (see Fig. 11) and by means of suitable illumination, determine the diameter of the transition circle with the aid of an optical limit gauge (B-l.5) placed in the micrometer eyepiece of a measuring microscope.

B-2.7.3 With the aid of special moulding plaster, make a cast of the bore or counterbore (see Fig. 12). Determine the distance between the two transmission points, where the footplate curvature joins the edge curvature, by observing the silhouette using an optical limit gauge (B-l.5) in the micrometer eyepiece of the measuring microscope.

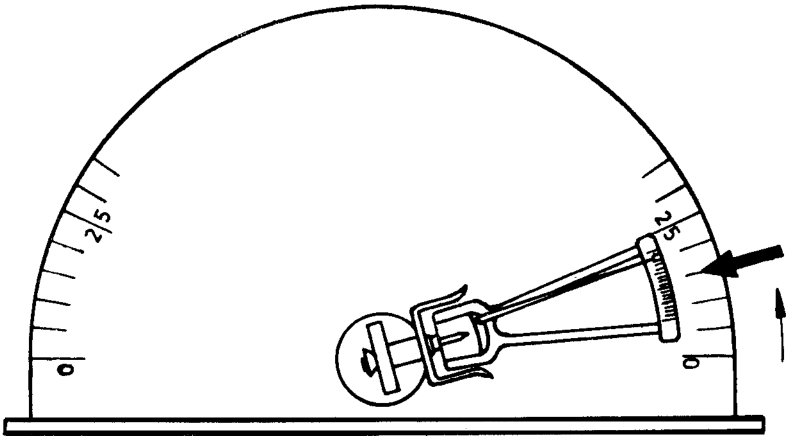


FIG. 7 MEASURING APPARATUS FOR TESTING FRICTION BETWEEN PLUNGER AND PLUNGER SLEEVE

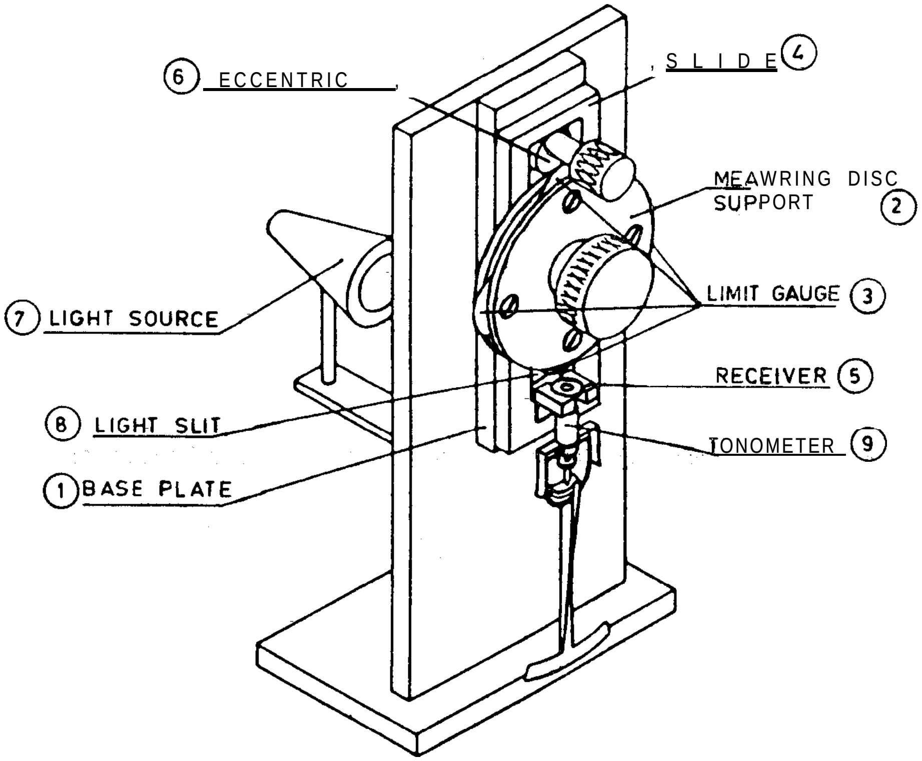
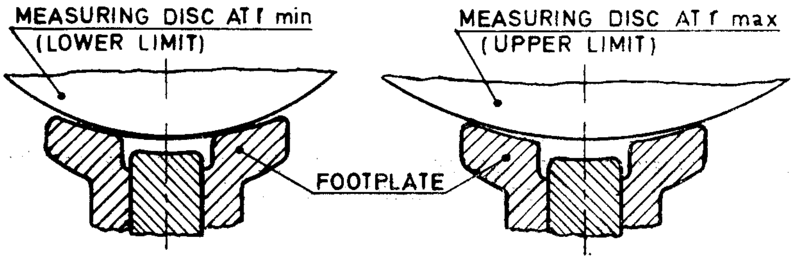
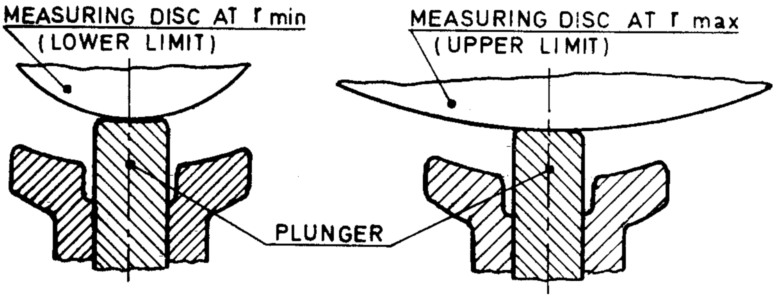


FIG. 8 TEST SET-UP FOR VERIFYING RADII OF CURVATURE OF THE FRONT SURFACES OF FOOTPLATB AND PLUNGER



9A Footplate



9B Plunger

FIG. 9 VERIFICATION OF RADII OF CURVATURE OF THE FRONT SURFACES OF FOOTPLATE AND PLUNGER

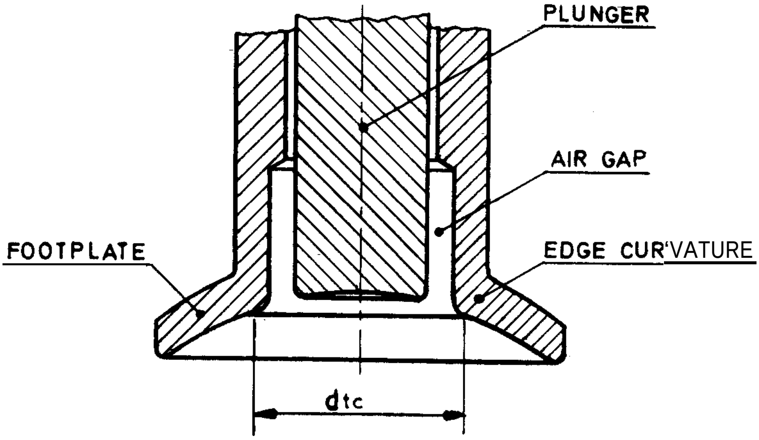


FIG. 10 PRINCIPLE FOR VERIFYING THE DIAMETER OF THE TRANSITION CIRCLE

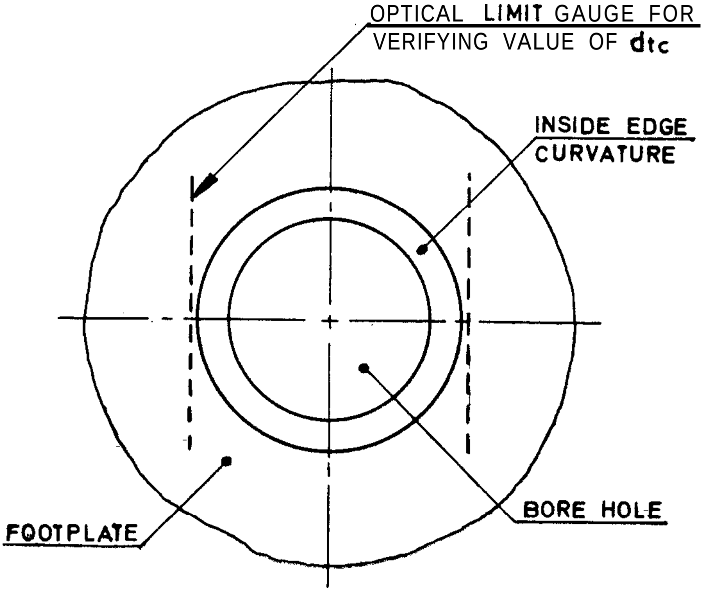


FIG. 11 VERIFICATION OF DIAMETER OF THE TRANSITION CIRCLE USING THE METHOD DESCRIBED IN B-2.7.2

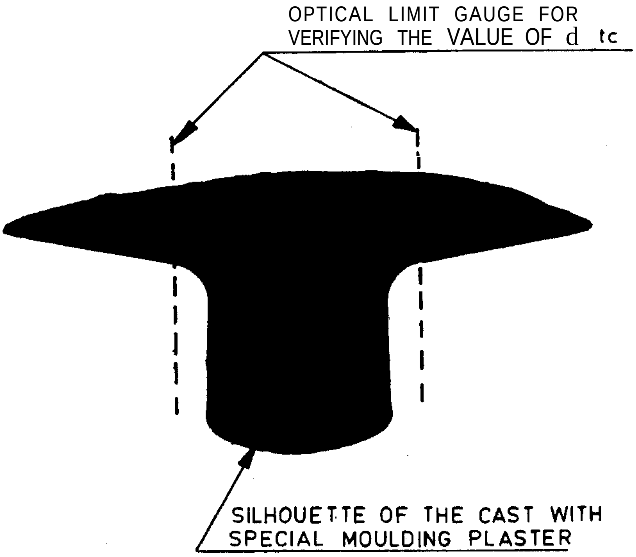

OPTICAL LIMIT GAUGE FOR VERIFYING THE VALUE OF d tc
SILHOUETTE OF THE CAST WITH SPECIAL MOULDING PLASTER

FIG. 12 VERIFICATION OF DIAMETER OF THE TRANSITION CIRCLE USING THE METHOD DESCRIBED IN B-2.7.3

B-2.7.4 Project two lines (that is, 'dividing lines' in Fig. 13) centrally onto the surface on the footplate. The distance between the lines is smaller than the diameter of the bore or counterbore. With the aid of a telescopic magnifier, examine the mirror image of the two lines and compare the diagonal distance of the marginal points, where the images of the dividing lines deviate from linearity, with the aid of the optical limit gauge (B-1.5).

B-2.7.5 The tonometer shall be deemed to comply with the dimensional requirements for the diameter of the transition circle, specified in 4.1.4 or 4.2.4, as appropriate, if the value of *dtc* is within the permitted dimensional tolerance limits.

B-2.8 **Curvature Radius of the Edge Curvature of the Plunger**

With the aid of the projector (B-1.6), produce the silhouette of the plunger front surface side on a plane. Compare the silhouette with an optical limit gauge (B-1.6). Apply the circle sectors one after another to the silhouette of the edge curvature of the plunger so that a small slit of light is to be seen (see Fig. 14).

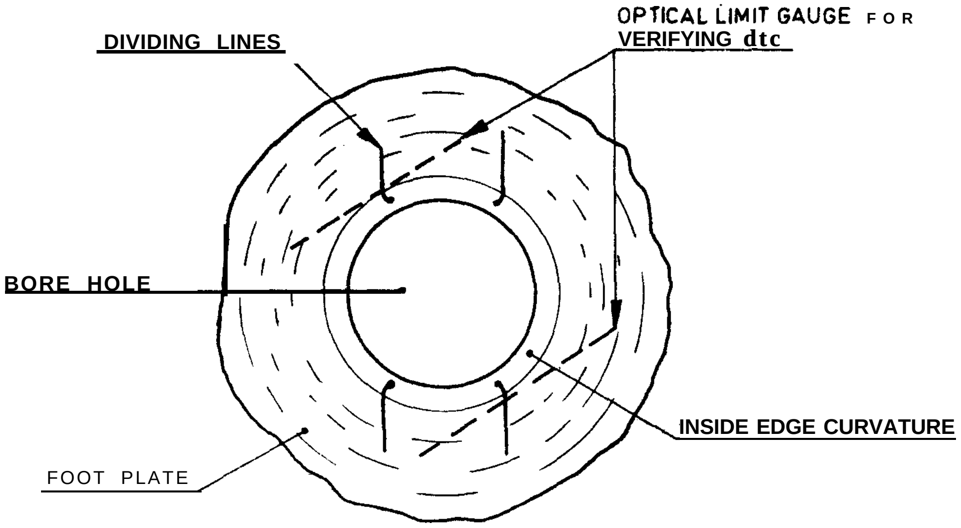


FIG. 13 VERIFICATION OF DIAMETER OF THE TRANSITION CIRCLE USING THE METHOD DESCRIBED IN B-2.7,4

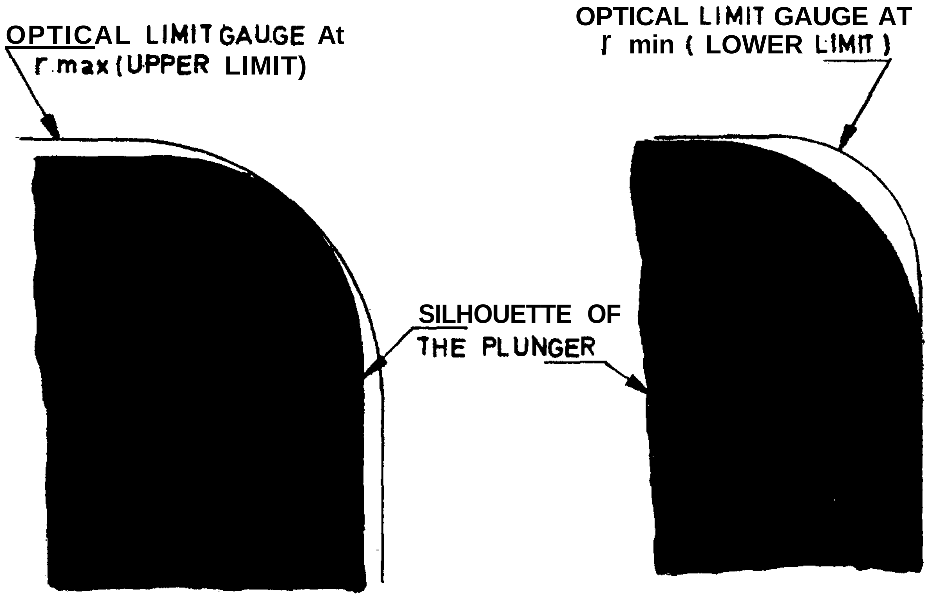

OPTICAL LIMIT GAUGE At r max (UPPER LIMIT)
OPTICAL LIMIT GAUGE AT r min (LOWER LIMIT)
SILHOUETTE OF THE PLUNGER

FIG. 14 VERIFICATION OF CURVATURE RADIUS OF THE EDGE CURVATURE OF THE PLUNGER

The tonometer shall be deemed to comply with the dimensional requirements for the radius of the edge curvature of the plunger, specified in 4.1.4 or 4.2.4 as appropriate, only if the radius is equal to or greater than the lower limit or if it is equal to or smaller than the upper limit.

B-2.9 Diameter of the Plunger on the Front Surface Side and the Outside Diameter of the Footplate

Determine the actual values for the diameter of the plunger on the front surface side and the outside diameter of the footplate with the aid of the micrometer (B-l.7) and compare with the corresponding dimensional requirements specified in 4.1.4 and 4.2.4.

The tonometer shall be deemed to comply with the dimensional requirements specified in 4.1.4 or 4.2.4, as appropriate, if the actual values determined are within the permitted dimensional tolerance limits.

B-2.10 Outside Diameter of the Spherical Front Surface of the Footplate

Compare the actual value for the outside diameter of the spherical front surface of the footplate with circle sector of the limit gauge (B-1.8.1, see Fig. 15), the width of which corresponds to the permitted minimum dimension, d_{Min}. For this purpose, place the gauge perpendicularly on the front surface of the footplate in an axial plane.

The tonometer shall be deemed to comply with the dimensional requirements specified in 4.1.4 or 4.2.4, as appropriate, if the outside diameter of the spherical front surface of the footplate is equal to or greater than d_{Min}.

B-2.11 Diameter of the Recess or Counterbore on the Front Surface Side

Remove the plunger from the tonometer. Test the recess or counterbore, respectively, with the cylindrical measuring gauge (**B-1.10**), the diameter of which corresponds to the dimensional tolerance. Test the depth of the recess with the aid of a measuring gauge provided with a ring, the permitted depth value being limited by the ring and the closing surface.

The tonometer shall be deemed to comply with the dimensional requirements specified in 4.1.4 or 4.2.4, as appropriate, if the measuring gauge enters without any play or does not enter the recess or counterbore, respectively, and if the depth of recess is within the dimensional tolerance limits.

B-2.12 Extension of the Plunger Below the Footplate

For measuring the extension of the plunger below the footplate, place the limit gauge (B-1.8.2, *see* Fig. 16) perpendicularly on the footplate from below in the plane of the axis, the tonometer being in an upright position.

The tonometer shall be deemed to comply with the dimensional requirements specified in 4.1.4 or 4.2.4, as appropriate, if the plunger does not extend further than the maximum height limit value, h_{Max}.

B-2.13 Width of the Dividing Lines on the Scale

Check the maximum width of the lines using the limit gauge (B-1.8.3).

The tonometer shall be deemed to comply with the requirements for the width of the dividing lines on the scale specified in **4.1.7** or 4.2.7, as appropriate, if the measured width is less than or equal to the width of the standard line.

B-2.14 Distance of the Pointer from the Scale

Test the distance of the pointer from the scale using the slip gauge (B-1.8.4).

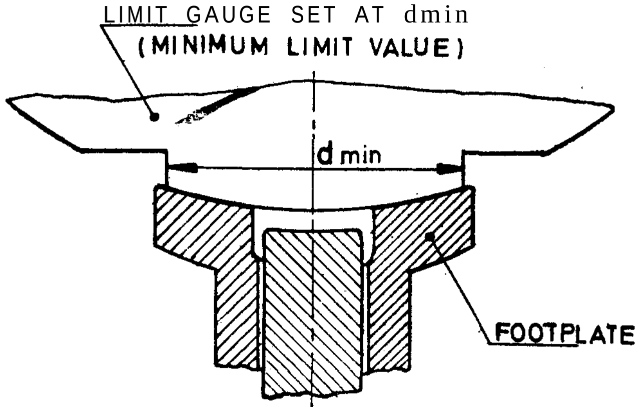


FIG. 15 VERIFICATION OF THE OUTSIDE DIAMETER OF THE SPHERICAL FRONT SURFACE OF THE FOOTPLATE

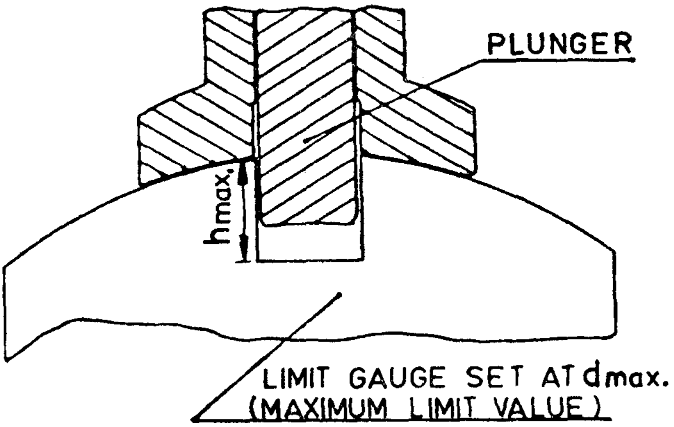


FIG. 16 VERIFICATION OF THE EXTENSION OF THE PLUNGER BELOW THE FOOTPLATE

The tonometer shall be deemed to comply with the requirements for the distance of the pointer from the scale specified in 4.1.8, if the slip gauge can be inserted between the pointer and the scale.

B-2.15 Scale Reading with the Lower Surface of the Lower at Right Angles to the Plunger Axis at Their Point of Contact

Remove the plunger from the tonometer. Insert the cylindrical measuring gauge (B-1.11) into the bore (see Fig. 17) to such an extent that the lever touches both the top edges of its front surface simultaneously. Check whether the pointer moves within the permitted scale range. This test may be dispensed within the case of tonometers the lower plunger surface of which has a convex curvature towards the top (epicycloid lever) or is provided with a sphere or a knife-edge.

The tonometer shall be deemed to comply with the requirements specified in 4.1.9, if the pointer moves within the permitted scale range at the setting specified above.

B-2.16 Scale Readings on the Test Blocks

Assemble the tonometer under examination so that it is ready for use. Place successively first on the test spheres (B-1.9) and then on the test block. Check to determine whether or not the indication is within the permitted tolerances.

The tonometer shall be deemed to comply with the requirements specified in 4.1.10 or 4.2.9, as appropriate, if the scale readings are within the tolerance limits specified.

B-2.17 Variation of the Scale Reading if the Plunger is Moved or Turned on the Lever

Place the tonometer on the test block and move the plunger laterally backwards and forwards in the bore hole or counterbore. Then rock the lever on its bearing and finally turn the plunger round on its longitudinal axis.

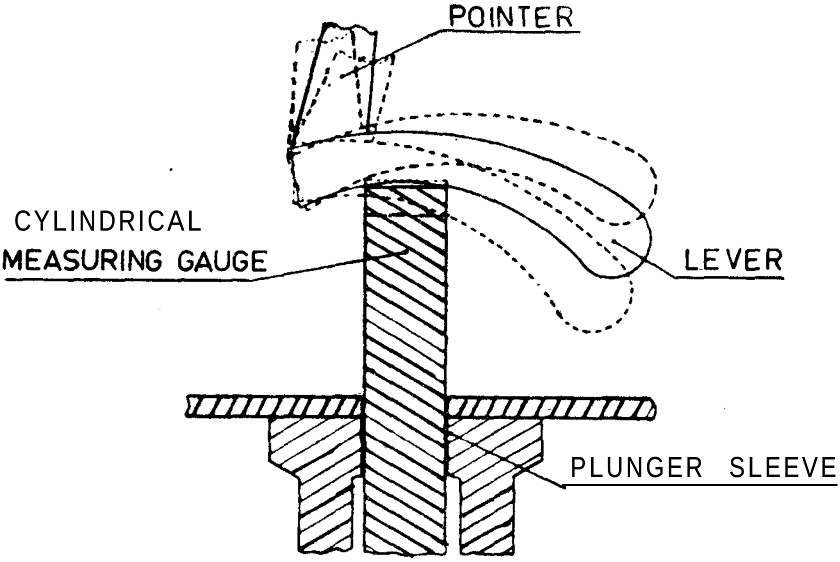


FIG. 17 **SET-UP FOR VERIFYING THE SCALE READINGS WITH THE LOWER SURFACE OF THE LEVER AT RIGHT ANGLES TO THE PLUNGER AXIS AT THEIR POINT OF CONTACT**

The tonometer shall be deemed to comply with the requirements specified in 4.1.10, if the scale readings do not vary by more than the permitted limits.

B-2.18 Variation of the Reading Between 15 and 30°C

This test should, in general, be carried out only once for each design.

Heat the complete tonometer in a temperature cabinet, for instance, at constant operating voltage. During this operation, place the measuring head on a test sphere. Check the scale reading of the tonometer.

The tonometer shall be deemed to comply with the requirements specified in 4.2.10.1, if the scale readings do not vary by more than the permitted limits.

B-2.19 Variation of the Reading in Case of Changing the Operating Voltage (applicable to mechanical-electrical tonometers)

This test should, in general, be carried out only once for each design.

Heat the tonometer to a constant temperature of 20°C. Place the tonometer measuring head on the test sphere. Subsequently change the operating voltage by ± 10 percent. Check the scale reading of the tonometer.

The tonometer shall be deemed to comply with the requirements specified in **4.2.10.2,** if the scale readings do not vary by more than the permitted limits.

B-3 TEST CERTIFICATE

B-3.1 The results of the verification testing, carried out in accordance with this Indian Standard, shall be given in a test certificate. An example of a test certificate is illustrated.

TEST CERTIFICATE FOR MECHANICAL AND MECHANICAL-ELECTRICAL IMPRESSION TONOMETERS

Tonometer No. : ____________________ Date: ____________

Sender: ____________________ Observer: ____________

Manufacturer: ____________________ Controller: ____________

	Requirement for Nominal Value	**Verification Result**
Effective weight of the plunger loaded by lever-pointer system		
At scale division ‘5’	5·50 ± 0·15 g	
At scale division ‘10’	5·50 ± 0·20 g	
Total mass of the tonometer without handle	16·5 ± 0·5 g	
Additional weights		
With inscription 7’5	2·0 ± 0·02 g	
With inscription 10’0	4·5 ± 0·02 g	
With inscription *15’0*	9·5 ± 0·02 g	
Friction between plunger and plunger sleeve	25” *Max*	
Friction between handle and handle sleeve	Does not affect movement	
Footplate		
Diameter	10’1 ± 0·2 mm	
Radius of curvature of the spherical front surface	15·0 ± 0·25 mm	
Outside diameter of the spherical front surface	9’0 mm *Min*	
Either		
Diameter of the recess or counterbore to a height of 1’5 mm *Min*	*3’3* mm *Max*	
Radius of the inside edge curvature	0’2 mm *Max*	
or		
Diameter of the transition circle (central area)	3’7 mm *Max*	
Polish surface condition, freedom from burrs	Clean, smooth, burr-free	
Plunger		
Diameter at the front surface up to a height of 1’5 mm *Min*	3·0 ± 0·03 mm	
Radius of curvature of the spherical front surface	15·0 ± 0·7 mm	
Radius of edge curvature	0·25 ± 0·015 mm	
Extension of the plunger	3’0 mm *Max*	
Polish, surface condition, freedom from burrs	Clean, smooth, burr-free	
Displacement of the plunger from scale reading		
Either		
Scale division ‘— 1’ to scale division ‘5’	0·30 ± 0·01 mm	
Scale division ‘— 1’ to scale division ‘10’	0·55 ± 0·02 mm	
Scale division ‘- 1’ to scale division ‘15’	0’80 ± 0·03 mm	
Scale division ‘— 1’ to scale division ‘18’	0’95 ± 0’05 mm	
Scale division ‘0’ to scale division ‘5’	0·25 ± 0·01 mm	
Scale division ‘0’ to scale division ‘10’	0·50 ± 0·02 mm	
Scale division ‘0’ to scale division ‘15’	0·75 ± 0’03 mm	
Scale division ‘0’ to scale division ‘18’	0·90 ± 0·05 mm	

	Requirement for Nominal Value	Verification Result
Lines on the scale		
Straight, of equal width, directed in the axis of the pointer		
Width of the lines	1/4 line distance/ 0·25 mm *Max*	
Pointer		
Width	Width of lines *Max*	
Overlapping of the lines	1/3 *Min;* not exceeded	
Distance from the scale	1 mm *Max*	
Angle between plunger and lever	*90”* at scale reading between scale division ‘5’ and ‘10’	
Scale reading		
Tested on test sphere with radius 14’75 mm	− 1 ±0·2 scale division	
	or −1·0±0·2 digital*	
Tested on test sphere with radius 16·00 mm	-0 ±0·2 scale division	
	or 0'0 ± 0’2 digital*	
Tested on test blocks enclosed	− 1 ± 0’2 scale division	
	0 ±0·2 scale division	
	15 ±0·2 scale division	
	or -1’0 $0’2 digital*	
	0’0 ±0·2 digital*	
	15·0±0·2 digital*	
Variation of scale reading		
With movement and turning of the plunger and movement of the lever if the tonometer is standing on the test sphere	0 4 scale division *Max* or 0’4 digital* *Max*	
Variation of scale reading		
With lateral movement and turning of the plunger	0’2 scale division *Max* or 0’2 digital* *Max*	
With temperature varying between 15 and 30°C (at constant operating voltage)	0·2 scale division *Max* or 0’2 digital” *Max*	
With operating voltage fluctuating ±10% (at constant temperature)	0·2 scale division *Max* or 0·2 digital* *Max*	

Remarks: ____

____

Result : Verified   Not verified   Signature ________________

---

*As indicated by the final digits.

ANNEX C

(*Clause* 1.3)

VERIFICATION OF THE REQUIREMENTS LAID DOWN FOR MECHANCCAL-OPTICAL AND MECHANICAL-ELECTRICAL APPLANATION TONOMETERS HAVING A CONSTANT DIAMETER APPLANATION CIRCLE (2, 8, 14 AND 17)

C-l APPARATUS

C-l.1 Optical Limit Gauge

For testing the diameter of the applanation circle, consisting of two pairs of lines; the distances between the lines of each pair correspond to the upper and lower permitted tolerance limits specified in 5.3.1. A dotted line traverses their midpoints (see Fig. 18).

C-l.2 Balance

For testing the measuring force, the reverse span at the transitional movement of the pressure body into the opposite direction, and for checking the position of the measuring arm with reference to its free space of movement at equilibrium of forces.

C-l.3 Limit Gauge

As described in B-1.8.3.

C-2 VERIFICATION PROCEDURES

C-2.1 Diameter of the Applanation Circle

Substitute the optical limit gauge (**C-l.1**) for the examined eye. Place the dividing line due to the prisms so as to coincide with a dotted line. For a pressure body without doubling prisms, determine the applanation circle diameter by means of a lined square. It shall be verified directly by comparison with the optical gauge.

The tonometer shall be deemed to comply with the tolerance requirements specified in 5.3.1, if the transposed line halves coincide or the transposed half line for the lower tolerance limit is outside the upper scale interval or inside the upper scale interval for the upper tolerance limit (see Fig. 19).

C-2.2 Measuring Force, Reverse Span and Central Position of the Tonometer Arm

In order to test the measuring force, place the applanation tonometer on the balance I (C-l.2) with the aid of a suitable holding device (see Fig. 20). To ensure that the contact between the applanation tonometer pressure body and the small contact wheel 6 of the balance is caused by the tonometer spring, place a mass of 0’5 g on the balance pan 2 and adjust the measuring force of the tonometer correspondingly. Then adjust the symmetric regulation of the tonometer arm amplitude using the three-coordinate fine adjustment. This can be checked by observing the position of the pointer 3 with reference to the zero index mark 4, deflecting the arm as far as both limits.

The adjustment of the contact point between the front surface of the pressure body and the small

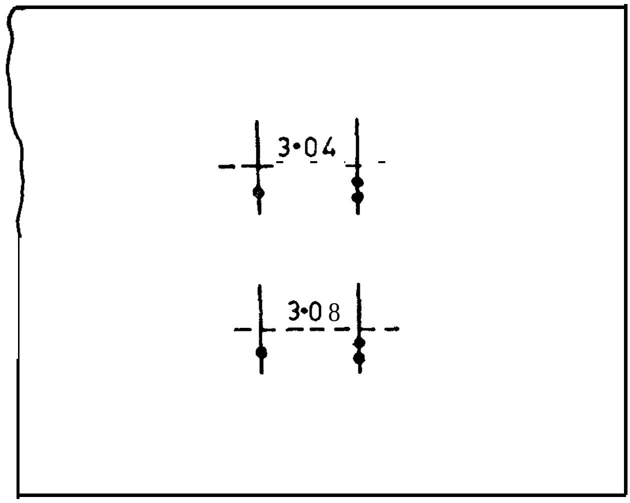


FIG. 18 OPTICAL LIMIT GAUGE FOR VERIFYING THE DIAMETER OF THE APPLANATION CIRCLE (IN THIS CASE SET FOR CONSTANT VALUE OF 3’06 mm)

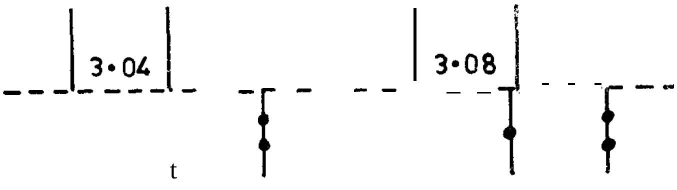
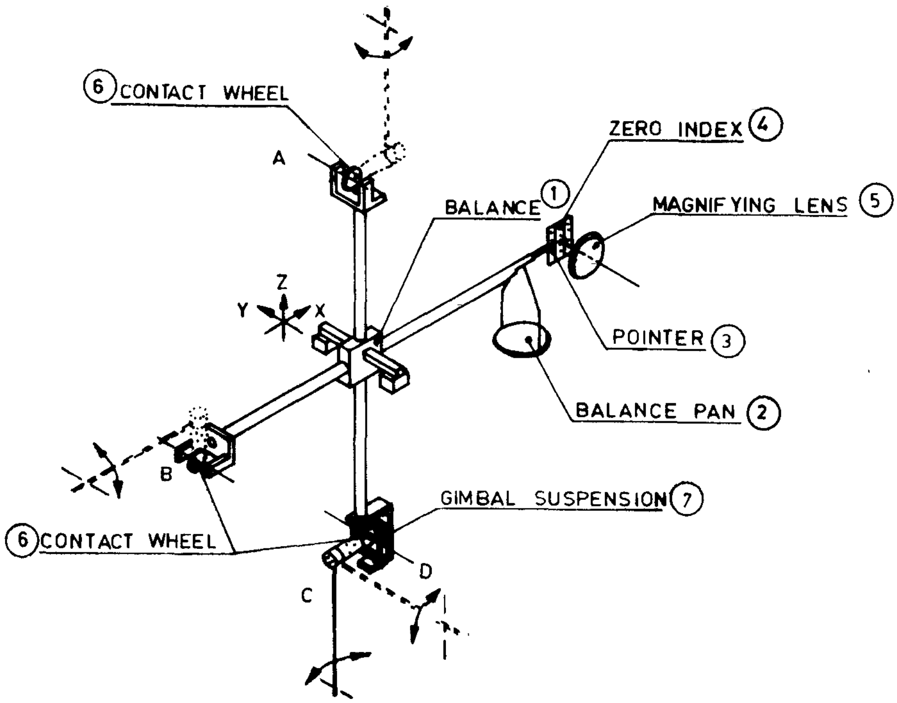


FIG. 19 VERIFICATION OF TOLERANCE LIMITS FOR THE DIAMETER OF THE APPLANATION CIRCLE (HAVING A CONSTANT VALUE OF 3’06 mm)



A TO D DIFFERENT TESTING DIRECTIONS

Fig. 20 Test Set-up for Verifying the Measuring Force

pivoted contact wheel follows the same principle so that contact is located in the centre of the applanation surface. The contact point can be made visible by using a very small drop of thin oil as shown in Fig. 21.

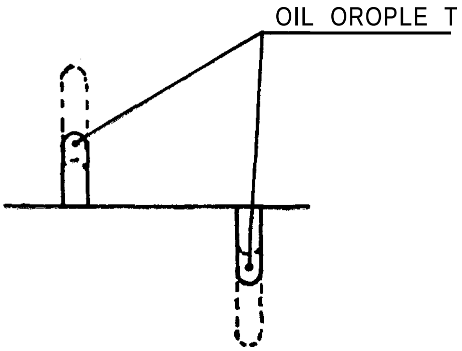


Fig. 21 Use of Oil Droplet to make Contact Point Visible

Successively place masses in steps of 1 g on the balance, from 1 g up to the maximum load. Increase the measuring force of the tonometer as the masses are added to the balance until the pointer again coincides with the zero index mark.

The test shall then be carried out starting with the maximum load and with the tonometer measuring force being decreased.

Adjusting and checking of the applanation tonometer shall be carried out using a low-vibration device.

The reverse span at the transition of the movement of the pressure body into the opposite direction is necessary due to the difference in the correlated measuring values of the increasing as compared with the decreasing measuring forces.

The tonometer shall be deemed to comply with the requirements specified in 4.3.3 and 4.3.5, if the deviations of the various values of the measuring force, read off the tonometer scale, from the theoretical values, do not exceed the permitted tolerance values and if the change of force required to move the pressure body in the reverse direction (reverse span) does not exceed the value specified in 4.3.3.

C-2.3 **Width of the Lines on the Measuring Drum**

Check the width of the lines using the limit gauge (C-1.3).

The tonometer shall be deemed to comply with the requirements specified in 4.3.4, if the measured width is less than or equal to the width of the standard line.

C-2.4 Variation of the Scale Reading of the Measuring Force Between 15 and 30°C

The test shall, in general, be carried out only once for each design.

Place the tonometer and the tonometer balance in a room in which the temperature can be adjusted, the readings within the range of measurement being a function of the temperature.

The tonometer shall be deemed to comply with the requirements specified in 4.3.5, if the scale readings do not vary by more than the permitted limits.

C-3 TEST CERTIFICATE

The results of the verification testing, carried out in accordance with the Indian Standard, shall be given in a test certificate. An example of a test certificate is illustrated.

TEST CERTIFICATE FOR MECHANICAL-OPTICAL TONOMETERS WITH CONSTANT DIAMETER OF THE APPLANATION CIRCLE

Tonometer No.: ________________ Date: ________________

Sender: ________________ Observer: ________________

Manufacturer: ________________ Controller: ________________

Diameter of applanation circle of nominal value 3’06 mm or……..mm ±0·02 mm

a) Pressure body No. 1…….mm Pressure body No. 2 ……..mm

Measuring force:

Initial state : The tonometer arm shall be adjusted symmetrically in the free space of movement with reference to the verification position.

Nominal Value Requirement	Error *	
	Horizontal	Vertical
9’81 ± 0’49 mN	________ mN	mN
19’61 ± 0’49 mN	________ mN	________ mN
29’42 ± 0’49 mN	________ mN	________ mN
39’23 ± 0’59 mN	________ mN	________ mN
49’03 ± 0’74 mN	________ mN	________ mN
58’84 ± 0’88 mN	________ mN	________ mN
68’65 ± 1·03 mN	________ mN	________ mN
78’45 ± 1’18 mN	________ mN	________ mN

Reverse span at the transition of the movement of the pressure body into the opposite direction: 0·29 mN *Max.* ________ mN

Position of the measuring arm with regard to its free play at equilibrium of force: Middle ________

Remarks: ________________

____

Results : Verified Not verified Signature ________________

---

*Error of the scale indication of the tonometer in measuring direction.

ANNEX D

(*Clauses* **1.3** *and* **4.5.3**)

VERIFICATION OF THE REQUIREMENTS LAID DOWN FOR AIR IMPULSE (PNEUMATIC) APPLANATION TONOMETERS (TYPE A)

D-l APPARATUS

D-l.1 Measuring Microscope

For checking the length, the internal diameter and the conicity of the nozzle in the centre of the objective. The measurement uncertainty of the microscope shall be less than 0'002 mm.

D-l.2 Torsion Balance

For checking the measuring force of the air impulse on a face 2'5 mm in diameter at a distance of 1 mm from the nozzle, that is, the optimum sharpness of the test mark in the ocular of the tonometer.

D-l.3 Control Balance

Having a sensitivity of 1 mg or better.

D-2 VERIFICATION PROCEDURES

D-2.1 Length, Internal Diameter and Conicity of Nozzle

Check these three parameters with the aid of the measuring microscope (D-l.1).

The length shall be checked in the axial section and the internal diameters by paraxial observation of the surfaces of the nozzle.

The diameter shall be determined three times, each time rotated by 60'.

The conicity shall be calculated from the difference of the mean internal diameter at both ends of the nozzle.

The tonometer shall be deemed to comply with the requirements for lengths inside diameter and conicity of the nozzle, if the measured values are in accordance with the dimensional requirements specified in 4.5.2.

D-2.2 **Measuring Force of the Air Impulse**

In order to check the measuring force, attach the measuring equipment shown in Fig. 22 to the supports of the head-rest of the tonometer. Mount the lens with a central cross 5, the torsion balance 6 (D-l.2) with a small plane mirror 7, having a diameter of 2'5 mm, and the control balance 11(D-1.3) on a cross-sliding carriage 4.

Adjust the nominal distance of 11 mm by the optimum focusing of the central cross, optically aligned with the axis of the objective 1, on the lens 5.

Replace the lens with the mirror 7 on the lower arm of the torsion balance 6 by shifting the measuring equipment sideways by the distance 1. When at rest, the axis of symmetry shall have an inclination of approximately 2" with respect to a direction per pendicular to the ocular axis, which can be adjusted with the aid of a stop screw IO. In this position, a parallel light beam emitted from the light source 2 is reflected on the mirror 7 in such a way that it does not fall on to detector 3.

Generate the measuring force necessary in each case by adjusting the torsion spring 8 using the knurled wheel 9. When within the measuring range, adjust the measuring forces and apply several different forces successively, in accordance with those given in Table 5. When an air impulse is released with each value, note whether the digital values displayed correspond to the values specified in Table 5 and the tolerances specified in 4.5.4.

After the air impulse has been released rotate the torsion 6 about its axis. At the moment when the mirror is in a vertical position with regard to the axis of the objective, that is, when the reflected light beam falls fully on to the detector 3, the force of the air impulse and the torsion force are in equilibrium.

Calibrate the torsion balance after the control balance has been shifted into the direction '*Bf*' until the upper arm of the torsion balance is frictionally connected with the ball and a force generated by a nominal mass on hook 13 and the force of the torsional spring are in equilibrium. This becomes obvious by the fact the mirror 7 is in a vertical position with regard to the axis of the objective.

Normally, the control balance is shifted into the direction 'B^-' *so* as not to influence the torsion balance.

The correlation between digital display and measured value of the force of air impulses shall also be verified for operation in the temperature range from 15 to 30°C (at constant operating voltage) and for operation with fluctuating operating voltage (at constant temperature of 20°C) (see 4.5.4).

The tonometer shall be deemed to comply with the requirements specified in 4.5.3 and 4.5.4, if the digital values displayed correspond to the respective measuring forces applied and are within the tolerance limits.

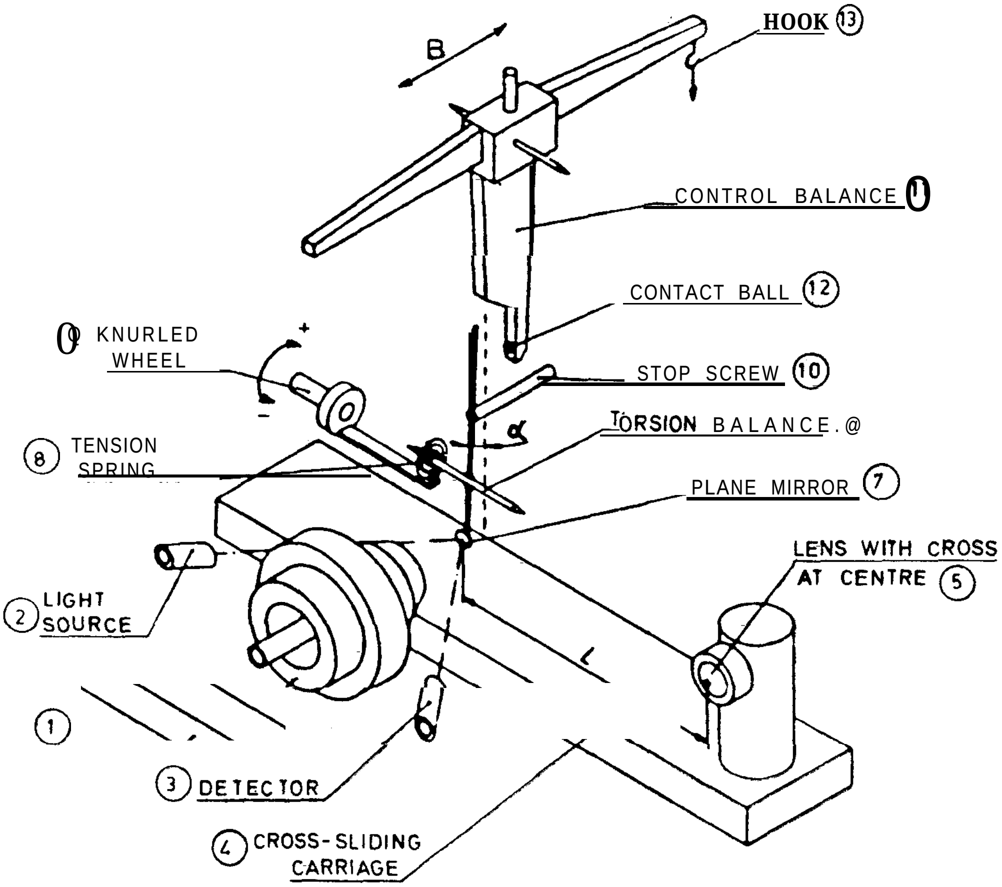
D-2.3 Radial Alignment

Adjust the tonometer to its measuring position in front of the lens. It is deemed to be properly radially aligned when the test mark (red -point; see Fig. 4) lies inside or does not extend beyond the centring ring (see Fig. 4) in any direction more than one-half of the diameter of the red point (see Fig. 22).

The digital read-out shall indicate ‘99’ (flashing) only when the tonometer is properly radially aligned. It shall not be possible to take measurements with the tonometer, if any one of the radial alignment criteria is exceeded.

D-3 TEST CERTIFICATE

The results of the verification testing, carried out in accordance with this International Standard, shall be given in a test certificate. An example of a test certificate is illustrated.



Fro. 22 Test Set-Up for Measuring the Force of the Air Impulse

TEST CERTIFICATE FOR AIR IMPULSE PNEUMATIC APPLANATION TONOMETERS

Tonometer No.: ________	Date : ________
Sender : ________	Observer: ________
Manufacturer : ________	Controller: ________

Nozzle	**Requirement**	**Verification Result**
Centred on the optical axis of the objective		
Length	27’305 ± 0’075 mm	________
Inside diameter	2 413 ± 0’010 mm	________
Conicity of inside diameter over total length	0’005 *Max*	________

Correlation between digital display and measured value of the force of the air impulse

Impulse directed on a face 2·5 mm in diameter at a distance of 11 mm from the nozzle

Nominal digital reading requirement	**Verification Result**
For 1’5 mN : 12 ± 1	________
For 15’3 mN : 30 ± 1	________
For 29.3 mN : 50 ± 2	________

Correlation between digital display and measured value of the force of air impulse

	Requirement	**Verification Result**
In the temperature range from 15 to 30°C (at constant operating voltage)		
Between the digits ‘ 12’ and ‘30’:	±1 in the final digit	________
Between the digits ‘3 1’ and ‘50’:	±2 in the final digit	________
During a change in the operating voltage of about 10% (at 20°C)	±1 in the final digit	________
Radial alignment		

Remarks: ________

____

Result : Verified Not verified Signature: ________

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